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This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

PATENT- OCH REGISTRERINGSVERKET

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AP: all, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LI, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

(21) *Patentansökningsnummer*
Patent application number
PCT SE04/00636

(86) *Ingivningsdatum*
Date of filing
2004-04-26

Stockholm, 2005-09-09

För Patent- och registreringsverket
For the Patent- and Registration Office

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Avgift
Fee *170:-*

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PCT REQUEST

Original (for **SUBMISSION**)

0	**For receiving Office use only**	
0-1	International Application No.	PCT / SE 2004 / 000636
0-2	International Filing Date	26 -04- 2004
0-3	Name of receiving Office and "PCT International Application"	The Swedish Patent Office PCT International Application
0-4	**Form - PCT/RO/101 PCT Request**	
0-4-1	Prepared Using	PCT-SAFE [EASY mode] Version 3.50 (Build 0002.162)
0-5	**Petition** The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	Swedish Patent Office (RO/SE)
0-7	**Applicant's or agent's file reference**	P 04-129/S
I	**Title of Invention**	DETECTION OF DIASTOLIC HEART FAILURE
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Original (for **SUBMISSION**)

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Original (for SUBMISSION)

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V	**DESIGNATIONS**	
V-1	**The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.**	
VI-1	**Priority Claim**	NONE
VII-1	**International Searching Authority Chosen**	Swedish Patent Office (ISA/SE)

VIII	**Declarations**	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	-	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	-	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	-	

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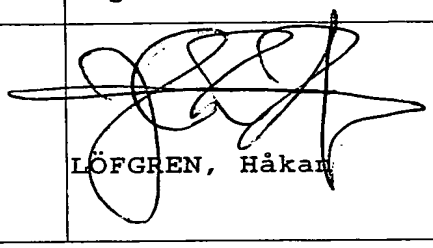
PCT REQUEST

Original (for SUBMISSION)

IX	Check list	number of sheets	electronic file(s) attached
IX-1	Request (including declaration sheets)	4	✓
IX-2	Description	7	-
IX-3	Claims	3	-
IX-4	Abstract	1	✓
IX-5	Drawings	4	-
IX-7	TOTAL	19 ✓	
	Accompanying Items	paper document(s) attached	electronic file(s) attached
IX-8	Fee calculation sheet	✓	-
IX-17	PCT-SAFE physical media	-	✓
IX-19	**Figure of the drawings which should accompany the abstract**	2	
IX-20	**Language of filing of the international application**	English	
X-1	**Signature of applicant, agent or common representative**		
X-1-1	Name (LAST, First)	LÖFGREN, Håkan	
X-1-2	Name of signatory		
X-1-3	Capacity		

FOR RECEIVING OFFICE USE ONLY

10-1	**Date of actual receipt of the purported international application**	26 -04- 2004
10-2	**Drawings:**	
10-2-1	Received X.	
10-2-2	Not received	
10-3	**Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application**	
10-4	**Date of timely receipt of the required corrections under PCT Article 11(2)**	
10-5	**International Searching Authority**	ISA/SE
10-6	**Transmittal of search copy delayed until search fee is paid**	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	**Date of receipt of the record copy by the International Bureau**	

ABSTRACT

An implantable medical apparatus for detecting diastolic heart failure, DHF, comprises a DHF determining device for determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient The DHF determining device comprises a pressure measuring means (2,10,12,16) for measuring pulse pressur in a cardiac cycle for a predetermined workload situation of the patient as said blood pressure parameter, and a comparison means (14) compares the measured pulse pressure with a predetermined reference value. A pacemaker comprises such an apparatus and control means (20) for optimising pacing therapy depending on th result of the comparison of the measured pulse pressures with said predetermined reference values. A corresponding method of detecting diastolic heart failure, DHF, comprises the step of determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient. This step of determining at least o blood parameter comprises determining, as said blood pressure parameter, the pulse pressure in a cardiac cycl for a predetermined workload situation of the patient, and the determined pulse pressure is compared with a predetermined reference value.

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PCT (ANNEX - FEE CALCULATION SHEET)

Original (for **SUBMISSION**)

(This sheet is not part of and does not count as a sheet of the international application)

0	**For receiving Office use only**	
0-1	International Application No.	PCT / SE 2004 / 000636
0-2	Date stamp of the receiving Office	26 -04- 2004

0-4	**Form PCT/RO/101 (Annex)** **PCT Fee Calculation Sheet**				
0-4-1	Prepared Using		PCT-SAFE [EASY mode] Version 3.50 (Build 0002.162)		
0-9	**Applicant's or agent's file reference**		P 04-129/S		
2	**Applicant**		ST JUDE MEDICAL AB		
12	**Calculation of prescribed fees**		fee amount/muliplier	Total amounts (SEK)	
12-1	Transmittal fee	T	⇨	1200	✓
12-2-1	Search fee	S	⇨	13870	✓
12-2-2	International search to be carried out by		SE		
12-3	International filing fee (first 30 sheets)	i1	8140		
12-4	Remaining sheets		0		
12-5	Additional amount	(X)	0		
12-6	Total additional amount	i2	0		
12-7	i1 + i2 =	i	8140	✓	
12-12	EASY Filing reduction	R	-580	✓	
12-13	Total International filing fee (i-R)	I	⇨	7560	
12-14	Fee for priority document Number of priority documents requested		0		
12-15	Fee per document	(X)	0		
12-16	Total priority document fee:	P	⇨		
12-17	**TOTAL FEES PAYABLE (T+S+I+P)**		⇨	22630	✓
12-19	**Mode of payment**		cheque		

DETECTION OF DIASTOLIC HEART FAILURE

Technical Field

The present invention relates to an implantable medical apparatus for detecting diastolic heart failure, DHF, comprising a DHF determining device for determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient. The invention also relates to a pacemaker provided with such an apparatus, and a method of detecting DHF, comprising the step of determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient.

Background

There is a growing recognition that congestive heart failure caused by a predominant abnormality in the diastolic function, i.e. diastolic heart failure, DHF, is both common and causes significant morbidity and mortality. Therefore early detection of DHF is important. Patients do not, however, seem to have symptoms at an early stage. In addition it has been hard to separate diastolic and systolic heart failure and they may also exist simultaneously.

It has been discovered that among the few parameters, separating diastolic heart failure from systolic heart failure, are certain blood pressure parameters obtained during work of the patient. Thus US 6 438 408 describes an implantable medical device for monitoring congestive heart failure, CHF. A plurality of heart failure parameters indicative of the state of the heart failure are measured employing EGMs, blood pressures including absolute pressures, developed pressures (= systolic pressures – diastolic pressures) and the time derivative dP/dt, as well as heart chamber volumes. One of these parameters is the relaxation or contraction time constant τ of the heart chamber. τ is calculated from a continuous pressure signal and is the drop in ventricular pressure at the end of systole and in the first part of diastole. The τ parameter is thus a general parameter reflecting the relaxation process.

According to an article by Dalane W. Kitzman et al., Pathophysiological Characterization of Isolated Diastolic Heart Failure in Comparison to Systolic Heart Failure, JAMA vol. 288, No. 17, 2144, November 6, 2002 the exercise pulse

pressure is one parameter separating systolic heart failure from diastolic heart failure.

The purpose of the present invention is to utilize this knowledge to propose a technique for detecting DHF, preferably at an early stage when the patient still does not seem to have any symptoms, based on measurement of pulse pressure under work.

Disclosure of the Invention

This purpose is obtained by an apparatus, a pacemaker and a method of the kind mentioned in the introductory portion of the description and having the characterizing features of claims 1, 10 and 13 respectively.

Thus with the present invention the reduced peak and submaximal exercise performance of DHF patients is utilized for detecting DHF. With the technique according to the invention it is possible to detect DHF at an early stage, often before the patient seem to have any symptoms.

In the present invention the workload situation of the patient must be identified, and therefore, according to an advantageous embodiment of the apparatus according to the invention, an activity sensor is provided for determining the workload of the patient.

According to another advantageous embodiment of the apparatus according to the invention an averaging means is provided to form an average value of pulse pressures during a plurality of cardiac cycles with said workload situation and an average value of pulse pressures measured during a plurality of cardiac cycles with the patient in rest. In this way the quality of the pulse pressure measurements is improved.

According to other advantageous embodiments of the apparatus according to the invention a wireless communication means is connected to said comparison means for automatically sending the results of the comparison of measured pulse pressures with said reference values to external receiver means, or a storing means is provided for storing the results of the comparison of measured pulse pressures with said reference values. Thus if the pulse pressure has risen above the reference value in a predetermined way this condition is automatically transmitted to a physician or stored for transmission in connection with a follow-up.

According to still other advantageous embodiments of the apparatus according to the invention said pressure measuring means comprise a pressure sensor adapted for placement in right ventricle or coronary veins of the patient's heart, and said pressure measuring means are adapted to determine maximum and minimum pressures in a cardiac cycle. It is preferred to place the pressure sensor in the right ventricle or the coronary veins, since the pressures in these places reflect the morphology of the left ventricular or aortic pulse pressure, especially with regard to maximum and minimum pressures.

The invention also relates to a pacemaker provided with the apparatus for detecting DHF and control means for optimising pacing therapy depending on the result of the comparison of said measured pulse pressures with said predetermined reference values. The pressure measuring means of the apparatus according to the invention then preferably comprises a pressure sensor connected to the pacemaker, since it can monitor the pulse pressure of its carrier for long periods. This is an advantage since evolvement of DHF is a slow process.

An advantageous embodiment of the pacemaker according to the invention comprises a rate responsive sensor for use as activity sensor for determining the workload situation of the patient. Even the pressure sensor of the pacemaker can be used as activity sensor.

According to an advantageous embodiment of the method according to the invention photo-plethysmographic signals are sensed for determining the pulse pressure, since it has been discovered that photo-plethysmographic signals obtained by a sensor placed close to the tissue where a pacemaker or ICD is implanted contain information about pulse pressure.

As mentioned above the measured pulse pressure is compared with a predetermined reference value, and according to an advantageous embodiment of the apparatus and the method according to the invention said pulse pressure in a cardiac cycle is measured for a predetermined workload situation and a rest situation of the patient, and the difference between said pulse pressures measured in said workload and rest situations is compared with a predetermined reference value for said difference for DHF detection. A condition of DHF is identified by a higher pulse pressure during workload than a patient with a systolic heart failure would have. The reference value for detection of DHF is preferably obtained from measurements on the patient at an early stage of the implantation period of the

apparatus or pacemaker. The patient is supposed not to suffer from DHF at the time of implantation. Therefore, according to an advantageous embodiment of the method according to the invention, pulse pressures are measured for different workloads of the patient and for the patient in rest at an early time, when the patient is not suffering from DHF, for determining said reference values. These pulse pressures from an early stage can also be measured for a certain period of time and typical pulse pressures during an identified workload and during rest are gathered and averaged and then stored for later use as reference values for comparison purposes. If later the measured pulse pressure, or average pulse pressure measured during several cardiac cycles, exceeds the reference value determined in this way by a prescribed amount x%, this is used as an indication of DHF.

Brief Description of the Drawings

To explain the invention in greater detail an embodiment of the invention will now be described with reference to the drawings on which figure1 is a diagram showing the left ventricular and aortic pressures as a function of time, figure 2 shows a block diagram of an embodiment of a pacemaker according to the invention, figure 3 is a flow chart illustrating the overall collection of pulse pressure data in an embodiment of the apparatus according to the invention, and figure 4 is a flow chart explaining in greater detail an example of the procedure for obtaining pulse pressure data according to the present invention.

Description of a Preferred Embodiment

In the following an embodiment of the invention using a pressure sensor will be described, and by the expression pulse pressure is meant the varying pressure in aorta during a cardiac cycle.

The above-mentioned pulse pressure can be obtained from the pressure measured in the left ventricle. In figure 1 the top curve shows the left ventricular pressure and the curve below the aortic pressure as a function of time. The magnitude of the pressures are indicated in arbitrary units in the figure.

The asterisks in the curves of figure 1 denote time points for the maxima and minima of the time derivative of the left ventricular pressure, $dLVP/dt_{max}$ and

$dLVP/dt_{min}$ respectively. As the aortic valves open close to the point $dLVP/dt_{max}$, the aortic pressure is close to the left ventricular pressure at this point of time.

During the period from $dLVP/dt_{max}$ to $dLVP/dt_{min}$ blood flows into aorta. The maximum of aortic pressure is situated in this period. The pulse pressure can consequently be obtained from left ventricular pressure by subtracting the pressure at the point of $dLVP/dt_{max}$ from the maximum of the left ventricular pressure obtained during the mentioned period.

If the conditions are such that pressure signals from other parts of the hemodynamic system are morphologically similar to the left ventricular pressure, these signals can also be used for determining the pulse pressure in the present invention, since only relative changes have to be determined for detecting DHF.

Figure 2 shows an embodiment of a pacemaker according to the invention comprising basic pacemaker circuits 20. A pressure sensor 2 is located in the right ventricle 18 of a patient´s heart and connected to the pacemaker 4. The signals from the pressure sensor 2 are supplied to an A/D-converter 10. After A/D-conversion the time derivative of the signal is formed in a derivation unit 16. The time derivative of the pressure signals are filtered in the low pass filter 12 before supply to the microprocessor and supporting circuits 14. Since time derivation promotes high frequency noise, it is advisable to eliminate in this way possible false peaks and valleys, which could be interpreted as $dLVP/dt_{max}$ and $dLVP/dt_{min}$. The filtered signals are supplied regularly into microprocessor and supporting circuits 14.

Located in the pacemaker 4 is an activity sensor 6 which is connected to an activity measuring unit 8 for determining the workload of the patient. A corresponding activity or workload signal is fed to the microprocessor and supporting circuits 14.

Figure 3 is a flow chart illustrating an example of the overall process for collecting pulse pressure data. The development of DHF is a slow process as mentioned. A timer, at 26 in figure 3, is therefore provided for activating pulse pressure measurements on a regular basis for reducing the current drain and releasing microprocessor power.

Collection of pulse pressure data is performed for different workloads of the patient, at 22 in figure 3. As mentioned above the collection process is activated by a timer, at 26, and therefore the process has to wait for activation by

the timer before starting, at 24. As the process is started, at 28, pulse pressure data are stored in different intermediate memory locations depending on the workload of the patient, at 30. Addresses to this memory locations are obtained from a table pointed to by the workload or activity measuring unit depending on the workload or activity,. at 32. Pulse pressure data from the intermediate memory is then stored in another memory according to the address obtained in the preceding step for later analysis, at 34 .

To improve the accuracy of the data stored the procedure of storing pulse pressure data can be performed by forming a floating mean value. One way to do this is to add a fraction 1/k of a new pulse pressure value P(i) to the pulse pressure value stored P_{stored} at the memory location pointed to by the activity measuring unit and form a mean value P_{store} according to the following equation

$$P_{store} = \frac{P(i) + P_{stored} \times (k - 1)}{k}$$

Figure 4 is a flow chart illustrating in greater detail the procedure for obtaining the pulse pressure. P_{max} and P_{min} denote temporary storages of maximum and minimum aortic pressures.

In order to start the pulse pressure measurements a QRS has to be detected , at 38 in figure 4, after reset of P_{max} and P_{min} , at 36. Pressure samples P(i) are then stored continuously together with the time derivative dP(i)/dt for comparison, at 40. A certain number of contiguous samples have to exist simultaneously, so that the above-mentioned filtering of the time derivative of the pressure is in accordance with the length of the filter coefficients. Care must be taken so that the delay in the filter influences the selection of corresponding pressure samples in a timely fashion, i.e. the pressure samples are picked with the same delay.

When dP/dt_{max} has been found, at 42 and 44, the pressure at that point in time is selected as the minimum pressure P_{min}. The pressure then rises in the aorta and the maximum pressure during systole occurs in the period between dP/dt_{max} and dP/dtmin, cf. the description of figure 1. In the process illustrated in figure 4 a simplified approach is used for determining maximum pressure P_{max}. Instead of determing the point of time for dP/dt_{min} a timer is started at the point of

dP/dt_{max}, at 46 in figure 4 and P_{max} is determined according to steps 48, 50, 52, 54 till timer overflow, at 56. Such a timer procedure is justified since the systolic time period in practice varies little. The pulse pressure is then obtained by subtracting P_{min} from P_{max}, at 58, which is the output of the process.

Instead of determining the pulse pressure with the aid of pressure sensors it can be determined by photo-plethysmography. Photo-plethysmographic signals from a sensor placed close to the tissue at the location of the implanted pacemaker or ICD contains information on pulse pressure. Thus such photo-pletysmographic signals can be used as an alternative for determining the pulse pressure.

CLAIMS

1. An implantable medical apparatus for detecting diastolic heart failure, DHF, comprising a DHF determining device for determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient, **characterized in** that said DHF determining device comprises a pressure measuring means (2,10,12,16) for measuring pulse pressure in a cardiac cycle for a predetermined workload situation of the patient as said blood pressure parameter, and a comparison means (14) for comparing the measured pulse pressure with a predetermined reference value.

2. The apparatus according to claim 1, **characterized in** that said pressure measuring means (2,10,12,16) are adapted to measure the pulse pressure in a cardiac cycle for a predetermined workload situation and a rest situation of the patient, and in that said comparison means (14) is adapted to compare the difference between said pulse pressures measured in said workload and rest situations with a predetermined reference value for said difference for DHF detection.

3. The apparatus according to claims 1 or 2, **characterized in** that an activity sensor (6) is provided for determining the workload of the patient.

4. The apparatus according to any of the preceding claims, **characterized in** that an averaging means (14) is provided to form an average value of pulse pressures during a plurality of cardiac cycles with said predetermined workload situation and an average value of pulse pressures measured during a plurality of cardiac cycles with the patient in rest.

5. The apparatus according to any of the preceding claims, **characterized in** that a wireless communication means is connected to said comparison means (14) for automatically sending the results of the comparison of measured pulse pressures with said reference values to external receiver means.

6. The apparatus according to any of the claims 1 - 4, **characterized in** that a storing means (14) is provided for storing the results of the comparison of measured pulse pressures with said reference values.

7. The apparatus according to any of the preceding claims, **characterized in** that said pressure measuring means comprise a pressure sensor (2) adapted for placement in right ventricle (18) or coronary veins of the patient´s heart.

8. The apparatus according to any of the preceding claims, **characterized in** that said pressure measuring means (2,10,12,16) are adapted to determine maximum and minimum pressures in a cardiac cycle.

9. The apparatus according to claim 1, **characterized in** that said pressure measuring means comprise a sensor for delivering photo-plethysmographic signals to be used for determing the pulse pressure.

10. A pacemaker, **characterized in** that it comprises an apparatus according to any one of the preceding claims and control means (20) for optimising pacing therapy depending on the result of the comparison of said measured pulse pressures with said predetermined reference values.

11. The pacemaker according to claim 10, **characterized in** that it comprises a rate responsive sensor (6) for determining the workload situation of the patient.

12. The pacemaker according to claim 10 comprising a pressure sensor, **characterized in** that said pressure sensor (2) is arranged as said activity sensor.

13. A method of detecting diastolic heart failure, DHF, comprising the step of determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient, **characterized in** that said step of determining at least one blood pressure parameter comprises determining, as said blood pressure parameter, the pulse pressure in a cardiac cycle for a predetermined workload situation of the patient, and in that the determined pulse pressure is compared with a predetermined reference value.

14. The method according to claim 13, **characterized in** that said pulse pressure in a cardiac cycle is measured for a predetermined workload situation and a rest situation of the patient, and the difference between said pulse pressures measured in said workload and rest situations is compared with a predetermined reference value for said difference for DHF detection.

15. The method according to claims 13 or 14, **characterized in** that an average value of pulse pressures is measured during a plurality of cardiac cycles with said predetermined workload situation and an average value of pulse pressures is measured during a plurality of cardiac cycles with the patient in rest.

16. The method according to any of the claims 13 – 15, **characterized in** that the results of the comparison of measured pulse pressures with said reference values are automatically sent to external receiver means.

17. The method according to any of the claims 13 -16, **characterized in** that the pulse pressure is measured in right ventricle or coronary veins of the patient´s heart.

18. The method according to any of the claims 13 - 17, **characterized in** that maximum and minimum pressures are determined in a cardiac cycle.

19. The method according to claim 13, **characterized in** that photo-plethysmographic signals are sensed for determining the pulse pressure.

20. The method according to any of the claims 13 - 19, **characterized in** that pulse pressures are measured for different workloads of the patient and for the patient in rest at an early time, when the patient is not suffering from DHF for determining said reference values.

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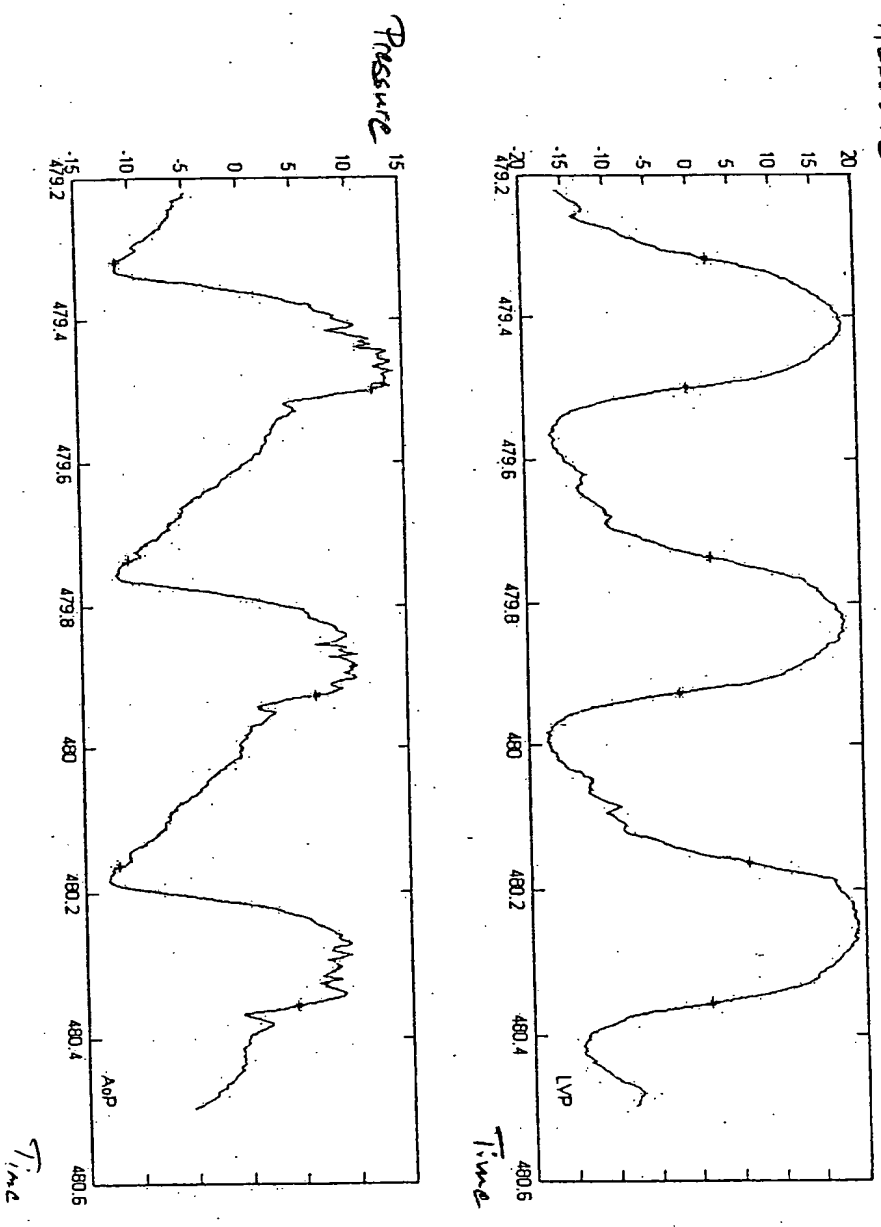
ABSTRACT

An implantable medical apparatus for detecting diastolic heart failure, DHF, comprises a DHF determining device for determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient. The DHF determining device comprises a pressure measuring means (2,10,12,16) for measuring pulse pressure in a cardiac cycle for a predetermined workload situation of the patient as said blood pressure parameter, and a comparison means (14) compares the measured pulse pressure with a predetermined reference value. A pacemaker comprises such an apparatus and control means (20) for optimising pacing therapy depending on the result of the comparison of the measured pulse pressures with said predetermined reference values. A corresponding method of detecting diastolic heart failure, DHF, comprises the step of determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient. This step of determining at least one blood parameter comprises determining, as said blood pressure parameter, the pulse pressure in a cardiac cycle for a predetermined workload situation of the patient, and the determined pulse pressure is compared with a predetermined reference value.

(Fig. 2)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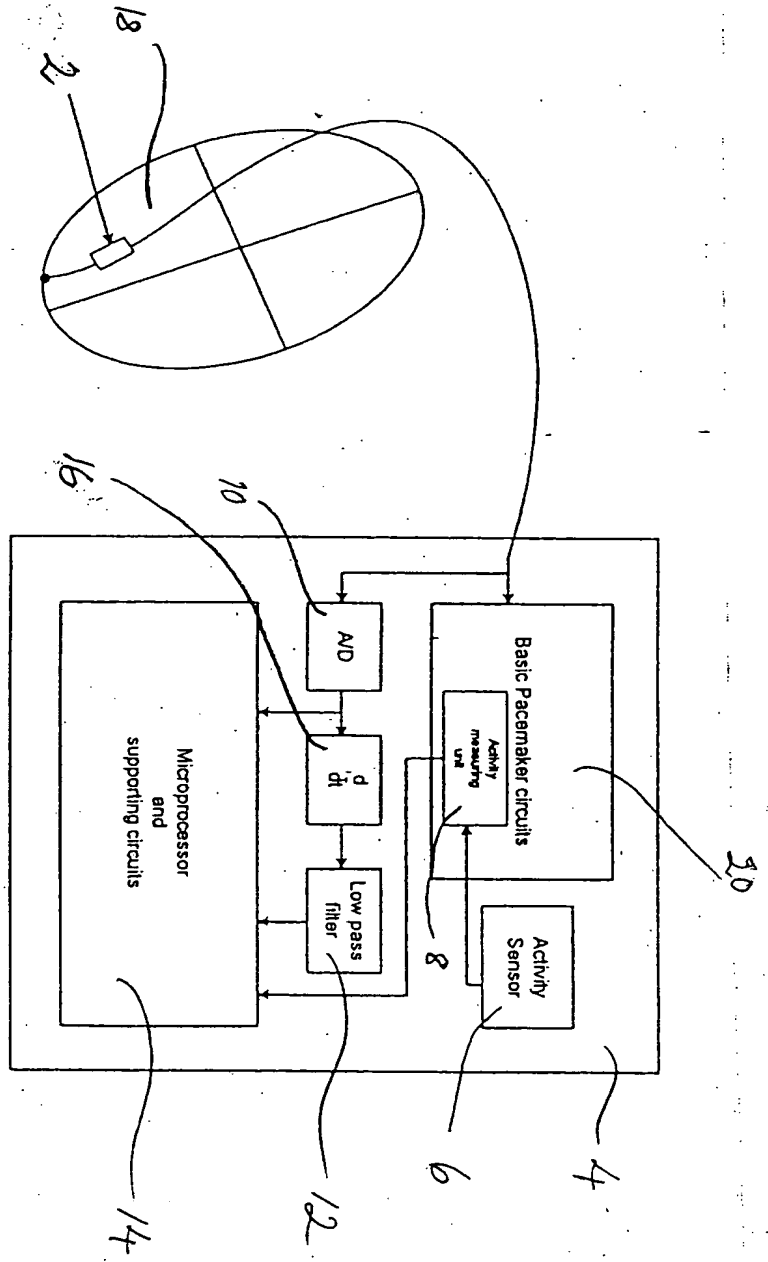
Time
AoP

Figure 1

Figure 2


18
2
16
10
A/D
d/dt
Low pass filter
Microprocessor and supporting circuits
Basic Pacemaker circuits
Activity measuring unit
Activity Sensor
8
20
6
4
12
14

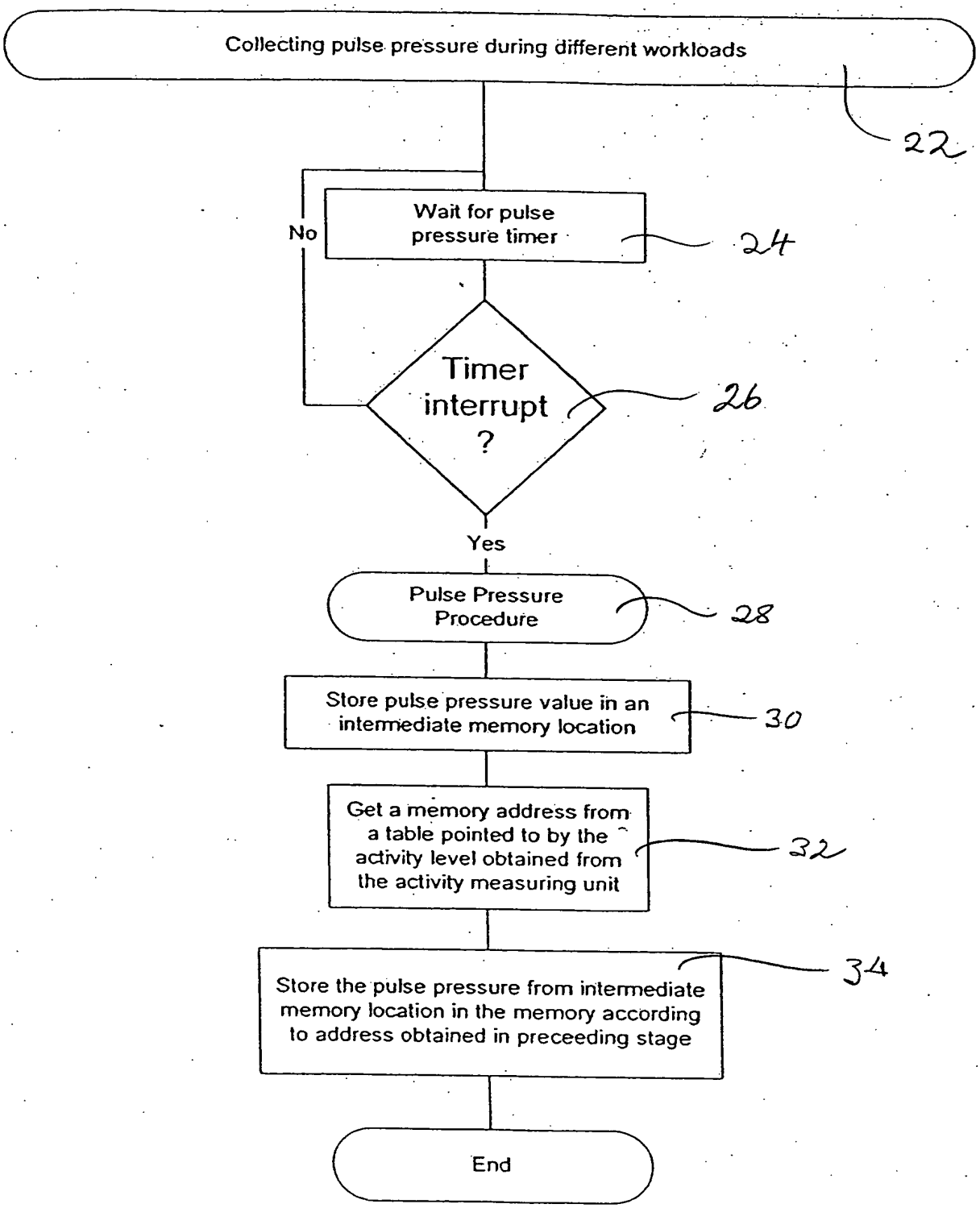

Collecting pulse pressure during different workloads
22
No
Wait for pulse pressure timer
24
Timer interrupt ?
26
Yes
Pulse Pressure Procedure
28
Store pulse pressure value in an intermediate memory location
30
Get a memory address from a table pointed to by the activity level obtained from the activity measuring unit
32
Store the pulse pressure from intermediate memory location in the memory according to address obtained in preceeding stage
34
End

Figure 3

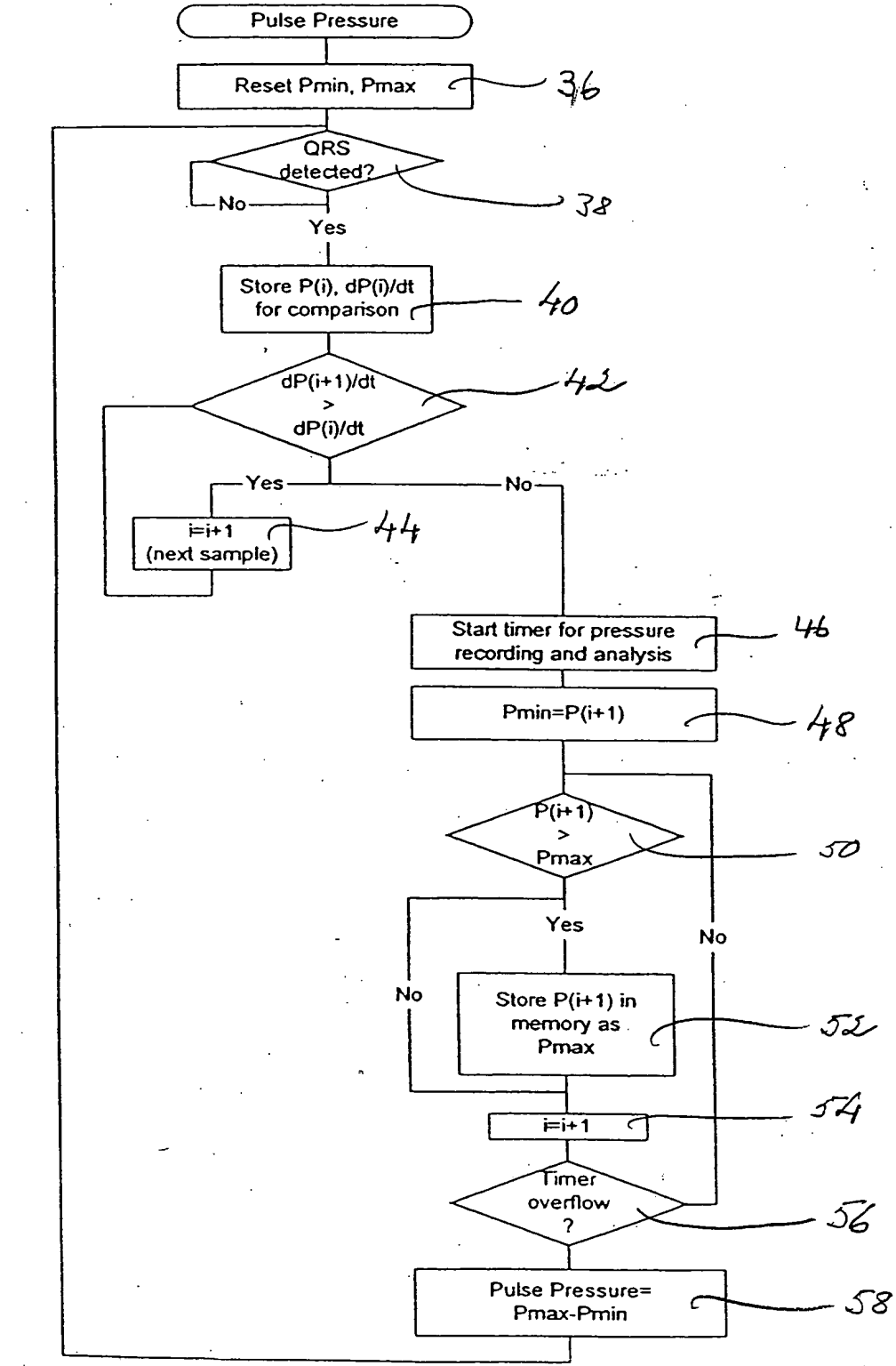

Pulse Pressure
Reset Pmin, Pmax
36
QRS detected?
No
Yes
38
Store P(i), dP(i)/dt for comparison
40
dP(i+1)/dt > dP(i)/dt
42
Yes
No
i=i+1 (next sample)
44
Start timer for pressure recording and analysis
46
Pmin=P(i+1)
48
P(i+1) > Pmax
50
Yes
No
No
Store P(i+1) in memory as Pmax
52
i=i+1
54
Timer overflow ?
56
Pulse Pressure= Pmax-Pmin
58

Figure 4